K092754

510(k) Premarket Notification
Summary of Safety and Effectiveness

JAN 19 2010

Submission Information

Manufacturer: Small Bone Innovations, Inc.
1380 South Pennsylvania Avenue
Morrisville, PA 19067
Ph: 215-428-1791 Fax: 215-428-1795

Submitted By: Small Bone Innovations, Inc.
John Minier
1380 South Pennsylvania Avenue
Morrisville, PA 19067

Proprietary Name: SBi Foot and Ankle Cannulated Screw System

Classification name: Class II, 21 CFR 888.3040 – Screw, Fixation, Bone

Product Code: HWC

Common/Usual Name and Reference Number:
Primary: Smooth or threaded metallic bone fixation fastener, 21 CFR 888.3040

Substantial Equivalence: Documentation is provided which demonstrated the SBi Large Cannulated Screw System to be substantially equivalent to other legally marketed devices.

Device Description: The SBi Foot and Ankle Cannulated Screw System consists of screws and washers that provide fixation of small and long bones. The devices are supplied non-sterile and are available in various sizes and configurations. There are several lengths and diameters of the cannulated screws washers appropriate to the screw diameter. There are fully threaded and partially threaded (16mm and 32mm of thread) configurations. The system also includes guide wires and instruments for use in implanting the screws.

Intended Use: The SBi Foot and Ankle Cannulated Screws and Washers are intended for fixation of small and long bones, such as femoral neck fractures; slipped capitol femoral epiphysis; tibial plateau fractures; ankle arthrodesis; pediatric femur fractures; intercondylar femur fractures; sacroiliac joint disruptions; and subtalar arthrodesis. The system is not intended for spinal use.

The implants are intended for single use only.

Materials: The implants are made from implant grade 316LS stainless steel (ASTM F138) in a set with several thread configurations in a range of lengths and will include the appropriate size washers of the same material. Another implant set is made from implant grade Titanium Alloy

(ASTM F136) which will consist of similar thread configurations and range of lengths and will include the appropriate size washers of the same material.

Predicate Devices: The subject devices are equivalent to Synthes 6.5mm and 7.0/7.3mm Cannulated Screws (K962011, K021932, K052483) and Howmedica Osteonics (Stryker) Asnis III 5.0mm, 6.5mm, and 8.0mm Cannulated Screws (K983006, K000080).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Small Bone Innovations, Inc.
% Mr. John Minier
Regulatory Affairs Director
1380 South Pennsylvania Avenue
Morrisville, Pennsylvania 19067

JAN 19 2010

Re: K092754
Trade/Device Name: SBi Foot and Ankle Cannulated Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fasteners
Regulatory Class: II
Product Code: HWC
Dated: December 23, 2009
Received: December 29, 2009

Dear Mr. Minier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Statement of Indications for Use

510(k) Number: K092754

Device Name: SBi Foot and Ankle Cannulated Screw System

Indications For Use:

The SBi Foot and Ankle Cannulated Screw System is indicated for fixation of small and long bones, such as femoral neck fractures; slipped capitol femoral epiphysis; tibial plateau fractures; ankle arthrodesis; pediatric femur fractures; intercondylar femur fractures; sacroiliac joint disruptions; and subtalar arthrodesis. The system is not intended for spinal use.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092754